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MediMattress
Better Care
A DIRECT HEALTHCARE GROUP COMPANY

EU Declaration of Conformity

issued under the sole responsibility of MediMattress Ltd (Legal Manufacturer) confirms the requirements specified in the EU Medical Device Regulation 2017/745 (MDR) have been fulfilled for products listed in Appendix I of this document.

Legal Manufacturer Information	*MediMattress Ltd* *Haukilahdenkatu 4* *00550 Helsinki* *Finland* *Business ID: 1480110-8* *EUDAMED SRN: FI-MF-000009089*
Medical Device Registration Agency	*The Finnish Medicines Agency (Fimea)*
General Product Trade Name(s)	*See Appendix I*
Intended Use of Medical Device(s)	*Supporting positioning therapy conducted by professional healthcare personnel or laymen, who is instructed by professional healthcare personnel in professional or domestic healthcare environments.*
Classification	*Class I (Rule 1 – Non-invasive devices)*
Assessment Route	*Annex II of the Medical Device Regulation (EU) 2017/745 (MDR)*
Applicable standards/ Common specifications	*See Appendix II*

Place and Date
Tampere, Finland - 8th of April 2022

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MediMattress Ltd

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Appendix I – Product Listing

Products:

Trade Name	Manufacturer REF	Basic UDI-DI (GMN)	EMDN Code
CaseClinic	20CCL	642981059120CCLSL	V080302
CaseSlow	20CSL	642981059120CSLU4	V08030102
CaseSupport	20CSU	642981059120CSUUN	V08030102
CaseTop	20CTO	642981059120CTOUD	V08030102
MegaGrip	40MGR	642981059140MGRVL	V08030102
MegaMemorest	40MME	642981059140MMEVC	V08030102
MegaPsoas	40MPS	642981059140MPSWH	V08030102
MegaRay	40RAY	642981059140RAYW9	V08030102
MegaRestabil	40MRE	642981059140MREVT	V08030102
MegaT	40MET	642981059140METVJ	V08030102
MegaQ	40MEQ	642981059140MEQVC	V08030102
MegaX	40MEX	642981059140MEXVS	V08030102
Mega7040	40MEG7040	642981059140MEG7040GC	V08030102
Mega18040	40MEG18040	642981059140MEG18040TJ	V08030102

Appendix II – Applicable Standards

Following standards are used to fulfil the beforementioned requirements (MDR):

Standard/Document Name	Description
EN ISO 13485:2016	Medical devices — Quality management systems
EN ISO 14971:2019	Medical devices — Application of risk management to medical devices
ISO 10993-1:2018	Biological Evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
EN ISO 15223-1:2020	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 3758:2012	Textiles — Care labelling code using symbols

Revision log

Version	Date	Author	Amendment
1.0	25/05/2021	LH	First issue MDR compliance
1.1	06/07/2021	LH	Updated Basic UDI-DI to GMN-format, added EUDAMED SRN-info
1.2	08/04/2022	LH	Updated GMDN to EMDN, corrected typos